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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/690,887	10/18/2000	Hiroaki Sagawa	1422-0442P	6993

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EXAMINER

GUZO, DAVID

ART UNIT PAPER NUMBER

1636

DATE MAILED: 02/28/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/690,885

Applicant(s)

SAGAWA ET AL.

Examiner

David Guzo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.

- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 03 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 20-28 is/are pending in the application.
- 4a) Of the above claim(s) 23-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 20-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

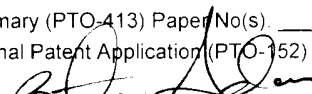
Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: 

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DETAILED ACTION

Applicants election of Group I, claims 20-22 is acknowledged. Claims 23-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 5.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sagawa et al. in view of Nordstrom et al.

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As best as can be determined, applicants claim a method for isolating a desired gene by cloning said gene (which can encode a product toxic to the cell) in a plasmid vector comprising a promoter sequence operatively linked to the desired gene, said promoter sequence being recognized by a RNA polymerase not inherent to the host cell and a replication origin for increasing copy number by induction with a exogenous factor. Essentially, applicants recite a tightly regulated system for cloning and expressing a gene whose product may be toxic to the host cell.

Sagawa et al. (Cited by applicants, *Gene*, 1996, Vol. 168, pp. 37-41, see whole article, particularly the Abstract and p. 39) recites a tightly regulated expression system in *E. coli* wherein the desired gene to be cloned and expressed can be toxic to the cell and wherein the promoter operatively linked to the desired gene is recognized by a RNA polymerase (SP6) not inherent to the host cell. Sagawa et al. does not teach a plasmid comprising a replication origin for increasing copy number by induction with an exogenous factor.

Nordstrom et al. (Cited by applicants, *Bio/Technology*, 1992, Vol. 10, pp. 661-666, see whole article, particularly pp. 661-662 and 665) recites the generation of runaway replication plasmids and uses thereof for amplifying plasmid DNA and increasing expression of gene products encoded by sequences present in the plasmids. Nordstrom et al. teaches that runaway replication can be induced by an exogenous factor such as increasing the temperature of the culture.

The claimed invention is essentially taught by Sagawa et al. with the exception of incorporating a replication origin for increasing copy number of the plasmid. The ordinary

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skilled artisan, seeking to develop a method for isolating genes which may encode products toxic to the cell would have been motivated to combine the teachings of Sagawa et al. on a tightly regulated plasmid expression system using a promoter operably linked to the gene of interest and recognized by a non-endogenous RNA polymerase (SP6), said plasmid designed to express toxic gene products in *E. coli*, with the teachings of Nordstrom et al. on the use of runaway replication plasmids to amplify the DNA contained in said plasmids for the expected benefit of increasing the copy number of the isolated (cloned) gene and increasing the level of expression of its product if so desired. It would have been obvious for the ordinary skilled artisan to do this because increasing the copy number of the plasmids taught by Sagawa et al. would yield more of the isolated (cloned) DNA for study and/or increase the level of expression of the product encoded by the desired gene. Given the teachings of the cited references and the level of skill of the ordinary skilled artisan at the time of applicants' invention, it must be considered that said ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

2. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sagawa et al. in view of Nordstrom et al. and further in view of Brooks et al.

Applicants claim a method for isolating a gene of interest wherein the gene encodes a toxic restriction endonuclease gene.

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Sagawa et al. and Nordstrom et al. are cited as in the above 35 USC 103(a) rejection of claims 20-21. Neither reference teaches that the desired gene to be isolated encodes a toxic restriction endonuclease.

Brooks et al. (U.S. Patent 5,137,823, issued 8/11/92, see whole document, particularly Columns 1-3) teaches the toxicity of many restriction endonucleases in host cells such as *E. coli* and the difficulty this entails in cloning of the genes encoding said endonucleases.

Sagawa et al. and Nordstrom et al. teach the claimed invention with the exception of the choice of the specific gene encoding

Sagawa et al. and Nordstrom et al. teach the claimed invention with the exception of the choice of the recited gene of interest. The ordinary skilled artisan would have been motivated to clone restriction endonuclease genes because these genes are known to be toxic to *E. coli* and other host cells and are of great importance in biotechnology (See Brooks et al., Columns 1-3). The isolation and cloning of these genes in host cells such as *E. coli* would therefore be of great value to the researcher in biotechnology. It would have been obvious for the ordinary skilled artisan to isolate (i.e. clone) genes encoding toxic restriction endonucleases in the tightly regulated runaway replication expression plasmid disclosed by Sagawa et al. and Nordstrom et al. because of the desirability of cloning important restriction endonuclease genes which are toxic to the host cells containing and expressing the cloned genes (as disclosed by Brooks et al.) and because the plasmids disclosed by Sagawa et al. and Nordstrom et al. are specifically designed to express cloned toxic gene products in *E. coli*. Given the teachings of the cited references and the

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level of skill in the art of the ordinary skilled artisan at the time of applicants' invention, it must be considered that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 20-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 (and dependent claims) recite a method for isolating a desired gene; however, claim 20 only recites properties of a plasmid vector and does not recite any specific method steps. Therefore, the claims are vague and indefinite.

Applicants request, on 10/18/00, for the Office to use the Computer Readable Form of the Sequence Listing in the parent application to prepare a Sequence Listing for this application is acknowledged. A Sequence Listing will be prepared.

No Claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding or relating to attachments to this Office Action should be directed to Patent Analyst Zeta Adams whose telephone number is (703) 305-3291.

David Guzo
February 25, 2002

DAVID GUZO
PRIMARY EXAMINER
David Guzo